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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 21 1997

WARNING LETTER

Wesley K. Herman, M.D.
Bradford B. Pazandak, M.D.
Vision Quest Laser Center
5421 La Sierra Drive
Dallas, Texas 75231-4185

Ref:OC:I4-1360

Dear Drs. Herman and Pazandak:

The Food and Drug Administration (FDA) inspected your medical practice on May 27 through 29 and June 3 through 6, 1997, and determined that you are using an unapproved excimer laser system manufactured by Edward Sullivan, an engineering consultant with Exsull, Drexel Hill, Pennsylvania, and representatives of Neuman MicroTechnologies, Inc., Bow, New Hampshire. This excimer laser system is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). Excimer laser systems are Class III devices which are required to have in effect an approved application for premarket approval (PMA) or an approved Investigational Device Exemption (IDE).

Medical devices used by physicians in the course of their practice to treat patients are "marketed" and "held for sale" within the meaning of the Act, and thus, are subject to the provisions of the Act. Your excimer laser system is adulterated under section 501(f)(1)(B) of the Act because it is a Class III device under section 513(f), which is required to have in effect an approved application for PMA or an approved IDE, and no such PMA or IDE is in effect for your excimer laser. Further, your continued use of this device to treat patients is also a violation of the Act.

In addition, your excimer laser system must comply with the requirements of the Federal Performance Standards for lasers which are found in Title 21 of the Code of Federal Regulations, (CFR) parts 1040.10 and 1040.11.

Section 538(a) of the Act, Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standards. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. To date, we have not received a Laser Product Report from Neuman MicroTechnologies or Mr. Edward Sullivan for this excimer laser system as required under CFR 1002.10. In addition, during the inspection several items of noncompliance with the federal laser product performance standard were observed and identified on the FDA 483 issued to you.

1. 21 CFR 1040.10(f)(2)(i). The defeatable interlocks were installed incorrectly so as to make them inoperable.

2. 21 CFR 1040.10(f)(3). The laser system lacks a remote interlock connector.

3. 21 CFR 1040.10(g)(7)(v). The laser system's protective housing lacks defeatably interlocked protective housing labels for each removable portion.

4. 21 CFR 1040.11(a)(3). The aperture label was incorrect and not placed in close proximity to the laser aperture. Please note that the aperture label for a medical laser product shall state, "Laser Aperture," rather than the phrase for nonmedical laser products specified in 21 CFR 1040.10(g)(5)(i).

5. 21 CFR 1040.10(h)(1) and 1040(a)(2). There was no Operation manual. Please note that written instructions for safe operation of the laser product are required by these sections. Section 1040.10(h)(1) specifies the instructions, warnings, label reproductions, and radiation information required, while 1040.11(a)(2) requires that calibration procedures and schedule be provided.

Please note that FDA does not consider your excimer laser to be a custom device. Section 520(b) of the Act establishes five conditions, each of which must be met by a device to be a custom device. The Act's custom device definition requires that the device be made to meet either the specific anatomical requirements of an individual patient or the special needs of an individual practitioner; a practitioner's special needs may be either an individual anatomical need or a special practice need that is not shared by other physicians.

We do not believe the requirements of your medical practice are unique because they are shared by numerous other health professionals. In addition, we do not believe your device is designed to meet any special anatomical needs that you or an individual patient of yours may have. Accordingly, your laser is not a custom device and is not exempt from the requirement under the Act that this device must have an approved PMA or IDE in effect.

Please notify this office within 15 working days of your receipt of this letter as to what, if any, actions you are taking, or plan to take, to bring your device into compliance with the Act. Your response should also clearly state whether or not you have ceased using the device to treat patients. Failure to immediately and completely cease clinical use of the device upon receipt of this letter and failure to bring your device into compliance with the Act, may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Please note that no extensions of the 15 day response period will be given.

Your response should be sent to the attention of Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch (HFZ-331) at the letterhead address. In addition, please send a copy of your response to Mr. J. Austin Templer, Compliance Officer, U.S. Food and Drug Administration, 3310 Live Oak Street, Dallas, Texas 75204. If you have further questions, please contact Mary-Lou Davis at (301) 594-4613 extension 127 or FAX: (301) 594-4638.

Sincerely yours,

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological Health